

REMARKS/ARGUMENTS

The preceding amendments and following remarks are submitted in response to the Office Action mailed November 1, 2005, setting a three-month shortened statutory period for response ending February 1, 2005. Claims 1-3, 6-7, 10-11, and 17 remain pending in the Application. Reconsideration, examination and allowance of all pending claims is respectfully requested.

Claims 1-3, 6-7, and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Tsugita et al.*, U.S. Patent No. 5,911,734 (hereinafter Tsugita) in view of *Pinchuk et al.*, U.S. Patent No. 6,254,633 (hereinafter Pinchuk). Applicants respectfully traverse this rejection. To establish a *prima facie* case of obviousness, there must be some motivation or suggestion present in the prior art to combine the references and each and every element of the claims must be present in the cited prior art. See M.P.E.P. §2143.01 and §2143.03.

As an initial matter, Applicants respectfully assert that there is no motivation or suggestion in the prior art to combine the cited references. As stated in M.P.E.P. §2143, “there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings.” At column 15, line 42 of Tsugita, it is stated “guidewire 40 includes a floppy atrumatic tip 204 which is designed to navigate through narrow, restricted vessel lesions.” The dilator tip of Pinchuk is described at column 5, lines 47-51 as having a tapered surface 34 which “expands the body lumen in advance of the remainder of the delivery system 20. In this manner, tortuous body lumens can more easily be navigated.”

It was asserted in the current Office Action that one of ordinary skill in the art would add a dilator tip such as the one in Pinchuk to the device shown in Figure 15. The Office Action states that it would be obvious to make such an amendment in order to "aid navigation of the delivery device." However, Applicants submit that one of ordinary skill in the art, given the presence of a distal tip that apparently provides for effective crossing of narrow portions of a patient's vasculature, would not substitute a dilator tip such as the one disclosed in Pinchuk, which apparently similarly provides for effective crossing of narrow portions of a patient's vasculature.

The fact that references can be modified or combined with another reference is not sufficient to establish a *prima facie* case of obviousness. Rather, there must be a motivation or suggestion for modifying or combining references. See M.P.E.P. §2143.01. Here, Applicants respectfully assert that there is no motivation or suggestion to substitute the tip design of Pinchuk in place of the tip design of Tsugita because these tip designs appear to both perform similar functions, and neither is apparently disclosed as being more effective than the other. One of ordinary skill in the art would not substitute a structure that performs a function for another structure that apparently performs a very similar function absent some additional motivation to do so. Applicants assert that no such motivation is present in the cited prior art. Because there is no motivation or suggestion to combine these references, Applicants respectfully assert that this combination of references cannot render the pending claims obvious.

Further, even if there were a motivation or suggestion to combine the cited references, Applicants assert that the two references together would not result in the claimed invention. According to the M.P.E.P. §2143.03, each and every element of the

claims must be present in the cited prior art in order to establish a *prima facie* case of obviousness. It was stated in the most recent Office Action that Tsugita discloses a filter system comprising a wire having a proximal end and a distal end, a filter for collecting debris from a body lumen having a support frame, an outer shaft, an inner shaft, and a coil spring adapted to cause radial expansion of the filter. It was acknowledged in the Office Action that Tsugita fails to disclose a dilator tip, but it was asserted that the Pinchuk reference discloses this feature. However, Applicants assert that each and every element of the rejected claims is not present in Tsugita, Pinchuk or a combination thereof.

In the previous Response, Applicants asserted that the cited references failed to disclose a coil spring that is adapted to bias the dilator tip in a distally advanced position or toward the distal end of the distal sheath, as recited in claims 1 and 17. It was asserted that the coil spring of Figure 15 of Tsugita is not adapted to bias the dilator tip distally as described in claims 1 and 17. In response, the Examiner disagreed with this assertion "because the coil spring 206 of the Tsugita et al. reference is adapted to bias the tip 204 as a result of the contraction or elongation of the coil spring 206." Applicants disagree with this position, and maintain that the coil spring 206 of Figure 15 of Tsugita is not disclosed as an element that biases the tip distally, but instead appears to actually bias the tip proximally. Thus, the combination of Tsugita and Pinchuk is missing at least a coil spring that is adapted to bias the dilator tip in a distally advanced position or toward the distal end of the distal sheath, and Applicants respectfully assert that this combination cannot render claims 1 and 17 obvious.

A description of the operation of a device according to the disclosure of Tsugita is given in the paragraph beginning at column 15, line 35. The coil spring is disclosed as

being "disposed helically about elongate member 207 in order to cause radial expansion of struts 203 upon deployment." In other words, the coil spring can apparently apply force to the structure in order to facilitate the radial expansion of the struts. In order to facilitate the movement of the struts outwardly, it appears that the coil spring must be biased to contract, or get shorter (thus the inward pointing lines shown in Figure 15). Applicants respectfully assert that such forces would not bias a tip portion in a distal direction.

As mentioned at column 15, line 47, "the elongate member 207 may be formed from a longitudinally stretchable material which compresses as the struts 203 expand radially." As an alternative, the elongate member 207 can apparently be disposed within second elongate member 201, allowing the effective length of elongate member 207 to be shortened when the struts expand. With the coil spring biased to cause the elongate member 207 to effectively become shorter, the coil spring actually appears to move the distal tip proximally relative to the rest of the device when it moves the struts to the expanded position, not distally. Thus, the coil spring would appear to be biased to cause the distal portion of the device to move proximally, not distally.

Further, in the most recent Office Action, it was asserted that the coil spring "is adapted to bias the tip as a result of the contraction or elongation of the coil spring." However, this is not what is required by the language of claims 1 or 17. Claims 1 and 17 recite language that requires a spring coil to be adapted to bias a dilator tip in the distally advanced position or toward the distal end of the sheath. In other words, it is the bias of the spring itself that exerts force on the dilator tip. It does not appear that the description of Figure 15 of Tsugita describes any embodiment that contains a spring that is biased to

place a distally directed force on a portion of the tip. Instead, as described above, the spring of Figure 15 of Tsugita appears to be adapted to bias the distal portion of the device in the proximal direction as it facilitates deployment of the struts, exactly the opposite of what is required by the language of claims 1 and 17. Thus, because at least this element is missing from the combination of Tsugita and Pinchuk, Applicants respectfully assert that claims 1 and 17 are not obvious in light of the cited references. Because they are dependent on claim 1 and because they recite additional patentably distinct elements, Applicants also assert that claims 2, 3, 6, 7, 10 and 11 are also allowable.

Further, at least one other element of claim 1 is missing from Tsugita as modified by Pinchuk. Specifically, even if a dilator tip is taken from Pinchuk and placed in the structure of Tsugita, the dilator tip would not appear to be "slidably disposed in the distal sheath and movable between a distally advanced position located at least in part beyond the distal sheath and a proximally retracted position," as required by claim 1. Applicants assert that it is not at all apparent how the structure of Tsugita modified with the dilator tip of Pinchuk would satisfy this portion of claim 1. Thus, Applicants again assert that claim 1 should be allowable over the cited references because these references do not contain each and every element of claim 1. Because they depend on claim 1 and because they recite additional patentably distinct elements, Applicants also assert that claims 2, 3, 6, 7, 10 and 11 are also allowable.

As mentioned above, claim 7 was rejected under 35 U.S.C. §103(a) as being unpatentable over Tsugita in view of Pinchuk. In the current Office Action, it was stated that Figure 15 of Tsugita shows that elongate member 201 is shorter than the wrapped

wire portion 202 of Figure 15. Applicants respectfully disagree that Figure 15 shows such a relationship between these elements. Figure 15 is apparently a view of the distal end of one embodiment of Tsugita. The distal end apparently contains a filter structure that can be advanced through a patient's vasculature to a target location with the second elongate member 201 extending proximally from the filter structure. The entire length of the second elongate member 201 does not appear to be shown in either Figures 15 or 15A. It appears that the vertical line on the left side of Figures 15 and 15A is meant to depict that the device extends to the left of the line. As further evidence that the device extends to the left of the vertical line, Figure 15 shows very little length of second elongate member 201 proximal of the first elongate member 207. When the wrapped wire portion 202 of the device is moved in a proximal direction, as shown in Figure 15A, more of the wire is shown because it is necessary to show the new location of the wrapped wire 202. Thus, Applicants assert that the entire second elongate member 201 is not shown in Figures 15 and 15A, and it cannot be said that second elongate member 201 is substantially shorter than the wrapped wire 202. Because Tsugita does not apparently disclose a filter system wherein the length of the inner shaft is substantially shorter than the length of the outer shaft, and Pinchuk does not disclose this missing subject matter, Applicants assert that claim 7 is not obvious in view of these cited references.

Claims 10 and 11 were objected to as being dependent upon a rejected base claim, but would otherwise be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants respectfully assert that since base claim 1 is allowable over the cited prior art, dependent claims 10 and 11 are also in condition for allowance.

Reexamination and reconsideration are respectfully requested. It is submitted that all pending claims are currently in condition for allowance. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at 612-677-9050.

Respectfully submitted,

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By their Attorney,

Date: Jan 4, 2006

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